



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2023-0265; FRL-11109-01-OCSPP]

Tris(2-chloroethyl) Phosphate (TCEP); Draft Risk Evaluation under the Toxic Substances Control Act (TSCA); Letter Peer Review; Request for Nominations of Expert Reviewers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is seeking public nominations of scientific and technical experts to review the draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP) conducted under the Toxic Substances Control Act (TSCA). The draft risk evaluation will be released for public review and comment in December 2023 through a separate *Federal Register* document and subsequently submitted for letter peer review by the expert reviewers.

DATES: Nominations should be submitted in time to arrive no later **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your nominations to the Peer Review Leader listed under **FOR FURTHER INFORMATION CONTACT**. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose public disclosure is restricted by statute. If your nomination may contain any such information, please contact the Peer Review Leader to obtain special instructions before submitting that information.

FOR FURTHER INFORMATION CONTACT: Contact the Peer Review Leader, Dr. Alaa Kamel, Mission Support Division (7602M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-5336; email address: kamel.alaa@epa.gov or call the main office: (202) 564-8450.

SUPPLEMENTARY INFORMATION:

I. General Information

A. What action is the Agency taking?

The Agency is seeking public nominations of scientific and technical experts that the EPA can consider for service as peer reviewers for the review of the “2023 Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP).” EPA will be soliciting comments from the reviewers on the approach and methodologies utilized in the draft 2023 TCEP risk evaluation.

This document provides instructions for submitting nominations for EPA to consider for reviewers. EPA will publish a separate document in the *Federal Register* in December 2023 to announce the availability of the draft risk evaluation and solicit public comments.

B. What is the Agency's authority for taking this action?

TSCA section 6(b) requires that EPA conduct risk evaluations on existing chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations (15 U.S.C. 2605(b)). The risk evaluation must not consider costs or other non-risk factors (15 U.S.C. 2605(b)(4)(F)(iii)). The specific risk evaluation process is set out in 40 CFR part 702 and summarized on EPA's website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>.

C. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, and disposal of chemical substances and mixtures, and/or those interested in the assessment of risks involving chemical substances regulated under TSCA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

II. Nominations for Peer Reviewers

A. Why is EPA seeking nominations for peer reviewers?

As part of a broader process for developing a pool of candidates for peer reviews, EPA is asking the public and stakeholder communities for nominations of scientific and technical experts that EPA can consider as prospective candidates to serve as peer reviewers. Any

interested person or organization may nominate qualified individuals for consideration as prospective candidates for this review by following the instructions provided in this document. Individuals may also self-nominate.

Those who are selected from the pool of prospective candidates will be asked to review the draft risk evaluation for TCEP and to help finalize the Letter Review report.

B. What expertise is sought for this peer review?

Individuals nominated for this peer review, should have expertise in one or more of the following areas: environmental fate assessment; environmental hazard assessment; human health toxicology with experience in cancer mode of action, reproductive toxicology, neurotoxicology, and renal toxicology; dose-response modeling; physiologically based pharmacokinetic (PBPK) modeling; and human or environmental exposure assessment, especially for susceptible life stages and subpopulations to environmental contaminants, and experience with particle versus gaseous partitioning and air deposition of semi-volatile organic compounds (SVOCs). Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this review.

C. How do I make a nomination?

By the deadline indicated under **DATES**, submit your nomination to the Peer Review Leader listed under **FOR FURTHER INFORMATION CONTACT**. Each nomination should include the following: Contact information for the person making the nomination; name, affiliation, and contact information for the nominee; and the disciplinary and specific areas of expertise of the nominee.

D. Will ad hoc reviewers be subjected to an ethics review?

Peer reviewers are subject to the provisions of the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635, conflict of interest statutes in Title 18 of the United States Code and related regulations. In anticipation of this requirement, prospective candidates will be asked to submit confidential financial information which shall fully disclose,

among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. EPA will evaluate the candidates' financial disclosure forms to assess whether there are financial conflicts of interest, appearance of a loss of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service.

E. How will EPA select peer reviewers?

The selection of scientists to serve as peer reviewers is based on the expertise needed to address the Agency's charge to the reviewers. No interested scientists shall be ineligible to serve by reason of their membership on any advisory committee to a federal department or agency or their employment by a federal department or agency, except EPA. Other factors considered during the selection process include availability of the prospective candidate to fully participate in the Letter Review, absence of any conflicts of interest or appearance of loss of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of loss of impartiality, lack of independence, and bias may result in non-selection, the absence of such concerns does not assure that a candidate will be selected to serve as a peer reviewer.

Numerous qualified candidates are often identified for the review. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives across reviewers. The Agency will consider all nominations of prospective candidates for service as peer reviewers that are received on or before the date listed in the **DATES** section of this document. However, the final selection of peer reviewers is a discretionary function of the Agency. At this time, EPA anticipates selecting 10-12 reviewers in the review of the designated topic.

EPA plans to make a list of candidates under consideration as prospective peer reviewers for this review available for public comment by late fall of 2023. The list will be available in the docket at <https://www.regulations.gov> (docket ID number EPA-HQ-OPPT-2023-0265).

III. Letter Review

A. What is the purpose of this Letter Review?

The focus of this Letter Review is to review the approach and methodologies utilized in the “2023 Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP).” Feedback from this review will be considered in the development of the final TCEP risk evaluation.

EPA intends to announce in December 2023, in the *Federal Register*, the availability of and solicit public comment on the draft risk evaluation, at which time EPA will provide instructions for submitting public comments for the Agency’s and Letter Peer Reviewers’ consideration.

B. Why did EPA develop these documents?

TCEP is a High-Priority substance undergoing the TSCA risk evaluation process after passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA.

TCEP has been primarily used in paint and coating manufacturing, and in polymers used in aerospace equipment and products. In the past it has also been used in commercial and consumer products, including fabric and textile, products, foam seating, and construction materials. TCEP may also be imported in articles intended for consumer use.

In August 2020, EPA published a final scope document for 20 High-Priority substances, including TCEP, outlining the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Agency expects to consider in its risk evaluation.

EPA is submitting the “2023 Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)” and associated supporting documents for Letter Peer Review. The Letter Peer Review will include review of the analysis of physical chemical properties, the fate of TCEP in the

environment, releases of TCEP to the environment, environmental hazard and risk characterization for terrestrial and aquatic species, and human health hazard and risk characterization for workers, consumers, and the general population. Specifically, EPA is seeking comment on the following issues:

- The list of considerations EPA used to arrive at the human health hazard confidence levels and the specific confidence levels chosen for individual human health hazard outcome (neurotoxicity, reproductive/developmental effects, kidney effects, and cancer) in the TCEP risk evaluation.

- Whether the approach used to estimate anaerobic degradation in the absence of data is appropriate for assessing anaerobic degradation in sediment.

- Use of the model, Web-based Interspecies Correlation Estimation (Web-ICE), to predict acute toxicity hazard values for aquatic species not represented in the available studies. This is the first time EPA has used Web-ICE in a TSCA risk evaluation. These predictions were used with available empirical data to create a Species Sensitivity Distribution (SSD). The SSD was used to calculate a hazardous concentration for 5% of species (HC_{05}). EPA is also using a data-driven way of accounting for uncertainty for environmental hazard and is soliciting comment on its characterization of this uncertainty, specifically its use of the lower bound of the 95% confidence interval of the hazardous HC_{05} .

- Human health hazard benchmark dose modeling of animal toxicity data for TCEP.

- The list of considerations EPA used to arrive at the human health hazard confidence levels and the specific confidence levels chosen for individual human health hazard outcomes (neurotoxicity, reproductive/developmental effects, kidney effects, and cancer) to quantitatively evaluate risk from TCEP.

- Use of several approaches for estimating exposures to humans and environmental receptors: (1) the use of Verner 2008 Multi-compartment model, which was used to assess TCEP exposure to infants through human milk for the first time in a TSCA risk evaluation; (2) the use

of Verner 2008 Multi-compartment model and associated uncertainties in extrapolating from the inhalation to oral routes of exposure; (3) the use of AERMOD model to estimate air deposition of TCEP. EPA has used AERMOD in previous TSCA risk evaluations; however, its use in estimating air deposition is novel for TSCA risk evaluations.

- Approach for modeling drinking water contamination from wells near municipal solid waste landfills, which is a new approach for TSCA risk evaluations.

C. How can I access the documents submitted for review to the SACC?

EPA is planning to release the “2023 Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP)” and all background documents, related supporting materials, and draft charge questions in December 2023. At that time, EPA will publish a separate document in the *Federal Register* to announce the availability of and solicit public comment on the draft risk evaluation and provide instructions for submitting written comments. These materials will be available in the docket at <https://www.regulations.gov> (docket ID number EPA-HQ-OPPT-2023-0265) and through the TSCA Scientific Peer Review Committees website. In addition, as additional background materials become available, EPA will include those additional background documents (*e.g.*, reviewers participating in this letter review) in the docket and through the website.

Authority: 15 U.S.C. 2625(h).

Dated: September 26, 2023.

Michal Freedhoff,

Assistant Administrator,

Office of Chemical Safety and Pollution Prevention.

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